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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,677	10/06/2004	Mark Parrington	API-01-20-US	4967

7590 06/12/2009  
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EXAMINER
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AEDER, SEAN E

ART UNIT	PAPER NUMBER
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1642

MAIL DATE	DELIVERY MODE
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06/12/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/510,677	<b>Applicant(s)</b> PARRINGTON ET AL.	
	<b>Examiner</b> SEAN E. AEDER	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30, 36 and 38-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36 and 44 is/are allowed.
- 6) ☒ Claim(s) 1-30, 38-43, and 45-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Detailed Action***

The Amendments and Remarks filed 5/18/09 in response to the Office Action of 11/17/08 are acknowledged and have been entered.

Claims 1-30, 36, and 38-50 are pending and are currently under examination.

***Response to Arguments***

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-30 and 38-43 remain rejected under 35 U.S.C. 101 for the reasons stated in the Office Action of 11/17/08 and for the reasons set-forth below.

Claims 1-30 and 38-43, as written, do not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. The term "expression vector" does not indicate the hand of man is required. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

In the Reply of 5/18/09, Applicant argues that the sequence of SEQ ID NO:28 is not naturally occurring and differs from previously known CEA sequences. Applicant

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further argues that compositions comprising expression vectors and pharmaceutical compositions are not naturally occurring.

The arguments found in the Reply of 5/18/09 have been carefully considered, but are not deemed persuasive. In regards to the argument that the sequence of SEQ ID NO:28 is not naturally occurring and differs from previously known CEA sequences, not every DNA sequence which has occurred naturally or will occur naturally is known. Therefore, polynucleotides comprising SEQ ID NO:28 encompass naturally occurring polynucleotides which either have or will occur. In regards to the argument that comprising expression vectors are not naturally occurring, viruses are naturally occurring expression vectors. In regards to the argument that pharmaceutical compositions are not naturally occurring, claims reciting that a product is a pharmaceutical composition indicates an intended use and is not considered a limitation to a claim.

It is noted that amending claims 1, 26, and 38 by placing the word “isolated” before “nucleic” would obviate this rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 45-50 remain rejected under 35 U.S.C. 102(b) as being anticipated by Paoletti et al (US Patent 5,833,975; 11/10/98) for the reasons stated in the Office Action of 11/17/08 and for the reasons set-forth below.

Paoletti et al teaches ALVAC poxvirus vectors comprising CEA antigen-encoding SEQ ID NO:145, which shares greater than 80% homology with instant SEQ ID NO:28, and the full complement thereof (see abstract and sequence comparison below, in particular). Paoletti et al further teaches said vectors further comprising a nucleic acid sequences including the costimulatory molecule B7.1 (line 58 of column 14, in particular). Paoletti et al further teaches compositions comprising said vectors and pharmaceutically acceptable carriers (see line 22 of column 8, in particular). In regards to instant claims 45-50, it is noted that the nucleic acids of SEQ ID NO:145 includes all nucleic acids of 421-1490 of SEQ ID NO:28 (A, T, G, and C).

In the Reply of 5/18/09, Applicant argues that the amended claims are not anticipated by Paoletti et al because the amended claims related to nucleic acids comprising SEQ ID NO:28.

The arguments found in the Reply of 5/18/09 have been carefully considered, but are not deemed persuasive. In regards to the argument that the amended claims are not anticipated by Paoletti et al because the amended claims related to nucleic acids comprising SEQ ID NO:28, the nucleic acids of claims 45-50 are not required to comprise the sequence set-forth as SEQ ID NO:28. Rather, the nucleic acids of claims 45-50 require an isolated nucleic acid molecule comprising a CEA-encoding nucleic acid sequence including at least nucleotides 421-1490 of SEQ ID NO:28. The nucleic

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acids of claims 45-50 do not require an isolated nucleic acid molecule comprising a CEA-encoding nucleic acid sequence including at least nucleotides 421-1490 of SEQ ID NO:28 in any particular order.

It is noted the following amendments to claim 45 would obviate this rejection: “An isolated nucleic acid molecule comprising a CEA-encoding nucleic acid sequence including at least **the sequence set-forth by** nucleotides 421-1490 of SEQ ID NO.:28”.

#### Comparison of instant SEQ ID NO:28 and SEQ ID NO:145 of Paoletti et al:

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Query Match          80.6%;   Score 1697.8;   DB 2;   Length 2349;
  Best Local Similarity  88.1%;   Pred. No. 0;
  Matches 1859;   Conservative    0;   Mismatches  247;   Indels    3;   Gaps
1;

Qy          1  ATGGAGTCTCCCTCGGCCCCCTCCCCACAGATGGTGCATCCCCTGGCAGAGGCTCCTGCTC  60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          184 ATGGAGTCTCCCTCGGCCCCCTCCCCACAGATGGTGCATCCCCTGGCAGAGGCTCCTGCTC
243

Qy          61  ACAGCCTCACTTCTAACCTTCTGGAACCCGCCCACTGCCAAGCTCACTATTGAATCC
120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          244 ACAGCCTCACTTCTAACCTTCTGGAACCCGCCCACTGCCAAGCTCACTATTGAATCC
303

Qy          121 ACGCCGTTCAATGTCGCAGAGGGGAAGGAGGTGCTTCTACTTGTCCACAATCTGCCCCAG
180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          304 ACGCCGTTCAATGTCGCAGAGGGGAAGGAGGTGCTTCTACTTGTCCACAATCTGCCCCAG
363

Qy          181 CATCTTTTTGGCTACAGCTGGTACAAAGGTGAAAGAGTGGATGGCAACCGTCAAATTATA
240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          364 CATCTTTTTGGCTACAGCTGGTACAAAGGTGAAAGAGTGGATGGCAACCGTCAAATTATA
423

Qy          241 GGATATGTAATAGGAACTCAACAAGCTACCCCAGGGCCCGCATACAGTGGTCGAGAGATA
300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          424 GGATATGTAATAGGAACTCAACAAGCTACCCCAGGGCCCGCATACAGTGGTCGAGAGATA
483

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Qy 360	301	ATATACCCCAATGCATCCCTGCTGATCCAGAACATCATCCAGAATGACACAGGATTCTAC
Db 543	484	 ATATACCCCAATGCATCCCTGCTGATCCAGAACATCATCCAGAATGACACAGGATTCTAC
Qy 420	361	ACCCTACACGTCATAAAGTCAGATCTTGTGAATGAAGAAGCAACTGGCCAGTTCCGGGTA
Db 603	544	 ACCCTACACGTCATAAAGTCAGATCTTGTGAATGAAGAAGCAACTGGCCAGTTCCGGGTA
Qy 480	421	TACCCGGAAGCTCCCTAAGCCTTCTATTAGCTCCAATAATAGTAAGCCTGTCTGAAGACAAA
Db 663	604	 TACCCGGAGCTGCCCAAGCCCTCCATCTCCAGCAACAACCTCCAAACCCGTGGAGGACAAG
Qy 540	481	GATGCCGTGCGCTTTTACATGCGAGCCCCGAAACTCAAGACGCAACATATCTCTGGTGGGTG
Db 723	664	 GATGCTGTGGCCTTCACCTGTGAACCTGAGACTCAGGACGCAACCTACCTGTGGTGGGTA
Qy 600	541	AACAACCAGTCCCTGCCTGTGTCCCCTAGACTCCAACCTCAGCAACGGAAATAGAACTCTG
Db 783	724	 AACAATCAGAGCCTCCCGGTGAGTCCCAGGCTGCAGCTGTCCAATGGCAACAGGACCCCTC
Qy 660	601	ACCCTGTTTTAACGTGACCAGGAACGACACAGCAAGCTACAAATGCGAAACCCAAAATCCA
Db 843	784	 ACTCTATTCAATGTGACAAGAAATGACACAGCAAGCTACAAATGTGAAACCCAGAACCCA
Qy 720	661	GTCAGCGCCAGGAGGTCTGATTTCAGTGATTCTCAACGTGCTTTACGGACCCGATGCTCCT
Db 903	844	 GTGAGTGCCAGGCGCAGTGATTTCAGTCATCCTGAATGTCTCTATGGCCCGGATGCCCCC
Qy 780	721	ACAATCAGCCCTCTAAACACAAGCTATAGATCAGGGGAAAAATCTGAATCTGAGCTGTCAT
Db 963	904	 ACCATTTCCCTCTAAACACATCTTACAGATCAGGGGAAAAATCTGAACCTCTCCTGCCAC
Qy 840	781	GCCGCTAGCAATCCTCCCGCCCAATACAGCTGGTTTGTCAATGGCACTTTCCAACAGTCC
Db 1023	964	 GCAGCCTCTAACCACCTGCACAGTACTCTTGGTTTGTCAATGGGACTTTCCAGCAATCC





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[illegible]

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Qy	1918	TTTATCGCCAAAATCACGCCAAATAATAACGGGACCTATGCCTGTTTTGTCTCTAACTTG
1977		
Db	2104	TTTATCGCCAAAATCACGCCAAATAATAACGGGACCTATGCCTGTTTTGTCTCTAACTTG
2163		
Qy	1978	GCTACTGGCCGCAATAATTCCATAGTCAAGAGCATCACAGTCTCTGCATCTGGAACCTTCT
2037		
Db	2164	GCTACTGGCCGCAATAATTCCATAGTCAAGAGCATCACAGTCTCTGCATCTGGAACCTTCT
2223		
Qy	2038	CCTGGTCTCTCAGCTGGGGCCACTGTCGGCATCATGATTGGAGTGCTGGTTGGGGTTGCT
2097		
Db	2224	CCTGGTCTCTCAGCTGGGGCCACTGTCGGCATCATGATTGGAGTGCTGGTTGGGGTTGCT
2283		
Qy	2098	CTGATATAG 2106
Db	2284	CTGATATAG 2292

***Allowable Subject Matter***

Claims 36 and 44 are allowed.

***Summary***

Claims 1-30, 38-43, and 45-50 are rejected.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/

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Primary Examiner, Art Unit 1642